CONCLUSIONS Our study showed that the transcatheter closure of large post tricuspid shunts in pediatric patients with severe PAH was safe, feasible and efficacious alternative to conventional surgery.

CATEGORIES STRUCTURAL: Congenital and Other Structural Heart Disease

KEYWORDS Congenital heart disease, Device closure, Pediatric cardiology

TCT-30

PREMIUM Trial: Double blind study of percutaneous closure of patent foramen ovale with the AMPLATZER® PFO Occluder as a treatment for migraine with or without aura

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BACKGROUND Population studies have identified a correlation between migraine and patent foramen ovale (PFO), and observational studies have reported that PFO closure results in improvement in migraine in some patients. The PREMIUM Trial was a randomized, sham-controlled, double blind study of percutaneous closure of PFO with the AMPLATZER® PFO Occluder (St. Jude Medical, Inc.) as a treatment for migraine with or without aura.

METHODS 230 subjects with medically intractable migraine with or without aura, who also had a patent foramen ovale (PFO), were randomized to either a sham procedure plus medical therapy (107) or percutaneous closure of the PFO plus medical therapy (123). Inclusion criteria for randomization included 6 - 14 days of migraine per month as assessed by a headache specialist, and failure (either lack of efficacy or intolerance) of 3 preventive medications and a significant right to left cardiac shunt (Spencer grade 4-5) determined by a screening TransCranial Doppler (TCD) intravenous agitated saline study. Subjects were randomized on the catheterization table after proof of a PFO was established, to device closure versus a sham control. Subjects and headache specialists were blinded to the randomization allocation. The primary efficacy endpoint was the responder rate percent defined as a 50% reduction in migraine attacks per month based on the diary during months 10-12 post randomization. Subjects in the control arm could receive the device after the 1-year blind was over. The primary safety endpoint was the proportion of subjects who experienced a device related serious adverse event through 1 year of follow-up.

RESULTS There was no difference in the responder rate between the device (38%) and the control groups (32%, p=0.3). The device was safe: there was 1/202 (0.5%) device related serious adverse event, which was a transient episode of atrial fibrillation. Secondary endpoint analysis showed a significant reduction in the total number of headache days (3.4 vs 2.0 days, p=0.03) in the device group. A subset analysis revealed that subjects for whom the majority of migraine attacks included aura had a particularly significant reduction in headache days (19/39, 49% responder rate vs 9/40, 23% responder rate, p=0.015). Complete remission of migraine occurred in 10.8% (8/74) of the device group and 1.5% (1/68) of controls who had a diagnosis of migraine with aura (p=0.02).

CONCLUSIONS Device closure of PFO can be performed safely, but did not result in a 50% or greater decrease in migraine attack frequency compared with a sham procedure, but there was a significant decrease in the mean number of headache days. Subgroup analysis suggests that individuals with aura occurring during the majority of their attacks may respond more favorably to PFO closure, and that a small but significant percentage of migraine with aura patients may experience complete remission of migraine.

CATEGORIES STRUCTURAL: Congenital and Other Structural Heart Disease

KEYWORDS Clinical Trial, Migraine, Patent foramen ovale

TCT-31

Title: Immediate and One Year U.S. IDE Trial Results of the New GORE® CARDIOFORM Septal Occluder for Transcatheter Closure of Secundum Atrial Septal Defects

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BACKGROUND The GORE® CARDIOFORM Septal Occluder (studied as GORE® Septal Occluder) was recently FDA approved for the transcatheter treatment of ostium secundum atrial septal defects. It is a low profile double disc device composed of a nitinol 5-wire frame, and covered with expanded polytetrafluoroethylene. We present the first data including both Pivotal and early Continued Access trial subjects with one year follow-up.

METHODS Patients were enrolled from 17 Pivotal and Continued Access U.S. sites in a prospective single arm trial. Follow-up was immediately post-procedure, and at scheduled intervals through one year. Endpoints included successful device placement, immediate and late closure success, and serious adverse events, including serious device-related events requiring reintervention.

RESULTS Between October, 2012 and January, 2014, 125 patients were enrolled with a median age of 7.4 years (range 2.4-78.6). Defects treated had a static diameter of 10.0±3.2mm (maximum 17mm), and stop flow stretched diameter of 12.2±3.2mm (range 5.7-17.5). Deficient retroaortic rim (< 5.0 mm) was present in 36.3%, multiple fenestrations in 18.4%, and atrial septal aneurysm in 10.4%. A CARDIOFORM Septal Occluder was successfully implanted in 92% of patients (115/125), with a serious adverse event rate of 0.8% at one year. Immediate closure success (0-2 mm residual shunt) was 98.3% and a 2.1-4 mm residual defect was present in 1.7%. Clinical closure success, defined as normalization of right heart size, was 100%. There were no cases of post-procedural embolization or reintervention.

CONCLUSIONS The GORE® CARDIOFORM Septal Occluder provides a new option for percutaneous closure of small and medium-sized secundum atrial septal defects, with high technical implant success, occlusion rate, and safety profile.

CATEGORIES STRUCTURAL: Congenital and Other Structural Heart Disease

KEYWORDS Atrial septal defect, Congenital heart disease, Occluder

TCT-32

Percutaneous Ventricular Restoration (PVR) therapy using the Parachute® Device in Patients with Ischemic Dilated Heart Failure: PARACHUTE III, European Post Market Trial, Two Year Results

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BACKGROUND Left ventricle (LV) remodeling after anterior wall myocardial infarction (AWMI) leads to increased LV volumes, myocardial stress, and ultimately heart failure (HF). Treatment options are limited for these high-risk HF patients. Aims: The primary objective is to continue to assess the long term safety of the CardioKinetix Parachute Implant System in the partitioning of the left ventricle in patients with heart failure due to ischemic heart disease.

METHODS One hundred patients with NYHA class II-IV HF secondary to AWMI, with akinetic or dyskinetic wall motion abnormality, and LV ejection fraction < 40%, were enrolled in Europe. The primary endpoint was site-reported procedural and device related MACE in real world use of the Parachute Implant through 5 years of clinical follow-up. In this report, two year data will be analyzed. Secondary endpoints included changes in LVESVi and LVEDVi.

RESULTS As of the last data cut in early 2015, an analysis which included 73 of the 100 PARACHUTE III patients, had a two year procedure / device related MACE rate of 9.2%. Two year follow-up of the full cohort of 100 patients will be available for the TCT conference in October 2015.

CONCLUSIONS The analysis of the post market data confirms the safety and longer term efficacy of the Parachute device in treating HF.